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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,817	09/17/2003	Harry A. Dugger III	3633-038-999	4051
20583	7590	01/06/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			HAGHIGHATIAN, MINA	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/663,817	DUGGER, HARRY A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mina Haghigatian	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The receipt of the Response and amendments filed 09/24/04 is acknowledged. Claims 14, 17-20 and 22 have been amended and claims 1-13 cancelled. Accordingly claims 14-22 are pending and under examination.

#### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 14 and 17 under 35 U.S.C. 102(b) as being anticipated by Kanios et al (5,719,197) is maintained.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claim 15-16 and 18-22 under 35 U.S.C. 103(a) as being unpatentable over Kanios et al (5,719,197) in view of Singer et al (5,364,616) is maintained.

#### ***Double Patenting***

The rejection of claim 20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of US Patent No. 6,676,931 is

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maintained. It is noted Applicant stated that when the claims are otherwise deemed allowable, necessary steps will be taken to overcome this rejection.

### ***Response to Arguments***

Applicant's arguments filed September 24, 2004 have been fully considered but they are not persuasive.

Applicant argues that Kanios is teaching compositions and methods for the topical administration of active agents to a mammal, in particular, anesthesia and local anesthetic agents.

Applicant states that Kanios describes its compositions as "flexible, finite, bioadhesive compositions for topical application", defining finite as non-spreading. Applicant is correct in stating that the invention of Kanios is essentially about topical application by a flexible or adhesive composition. However, it is stated that preferred embodiments do not teach away from a broader disclosure. See *In re Susi*. As mentioned in previous Responses and Office Actions, Kanios is teaching other forms of compositions including liquid sprays. Applicants attention is drawn to column 9, lines 19-27, where Kanios recites "For example, in ONE embodiment, the anesthetic agents are dissolved in a solvent.....and then added to an adhesive .In ANOTHER embodiment, the resulting mixture is in cream, gel...., spray solution or other non-finite composition....". Also in column 10, lines 57-65, Kanios discloses that ".....when a non-finite carrier such as an ointment, gel, lotion...or spray-solution is used".

It is further noted that the instant claims are “composition” claims, and the product’s properties are considered inherent. Therefor if Kanios is disclosing a formulation containing the same ingredients as the instant claims are reciting, then it is taken that both formulations will be absorbed systemically once administered to the oral mucosa. It is also noted that “for transmucosal absorption” is considered intended use and is not given weight during examination. Kanios, therefor, teaches the formulations and the method of administration.

With regards to Singer’s reference, Applicant argues that the formulations of Singer do not remedy the deficiencies in Kanios. The reasoning is that Kanios is disclosing a finite composition and not a sprayable solution. As mentioned above, Kanios does disclose solutions for spraying and teaches mucosal absorption and application.

Applicant argues that that there is no motivation to combine the disclosures of Kanios and Singer. Kanios is clearly teaching a spray solution formulation containing an active, a solvent and an additive such as flavoring agent, which may be administered to the oral mucosa. Singer is teaching formulations in a spray solution form which include an active, a solvent and a flavoring agent such as oil of peppermint, and discloses suitable concentration ranges for the flavoring agents. Clearly one of ordinary skill in the art, given the formulations of Kanios would be motivated to look in the art for specific flavoring agents and a suitable concentration range because both formulations are

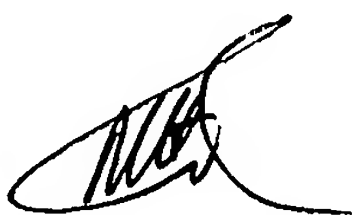
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sprayed in the oral cavity and flavor in such formulations is an important factor in patient compliance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

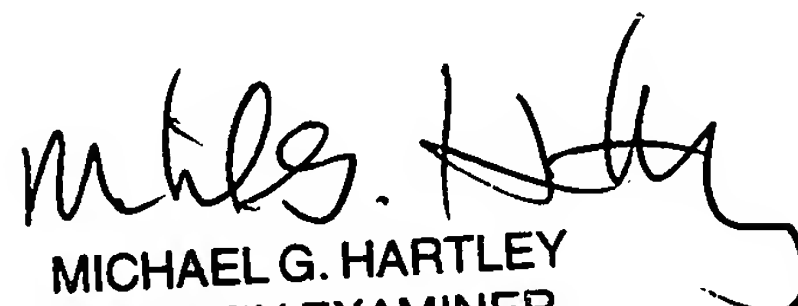
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian

December 22, 2004



MICHAEL G. HARTLEY  
PRIMARY EXAMINER